ARGUMENTS/REMARKS

Continued examination and favorable reconsideration are respectfully requested.

Claims 1-5, 8-16, and 18-26 are pending in this application. Claims 1-3, 11-16, and 18-26 are withdrawn from consideration. By this Amendment, claims 4, 9, and 10 have been amended.

Rejection of claims 4, 8, and 9 under 35 U.S.C. §112

At page 2 of the Office Action, the Examiner maintains the rejection of claims 4, 8, and 9 under 35 U.S.C. §112, first paragraph, for the reasons set forth in the previous Office Action. The Examiner states that because the claims do not recite a nucleic acid "comprising" SEQ. ID NO: 3, claims 4, 8, and 9 read on fragments of SEQ ID NO: 3. The Examiner states that the claims are not enabled to make a fragment of SEQ. ID NO. 3 that is present in the nucleus and which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene or a gene product. The Examiner states that undue experimentation would be required to identify fragments that encode a protein with the claimed functions. The rejection is respectfully traversed.

By way of this Amendment, the phrase "is set forth in" appearing in claims 4 and 9 has been replaced with the term "comprises."

Accordingly, this rejection should be withdrawn.

Rejection of claims 4, 8, and 9 under 35 U.S.C. §112

At pages 3-5 of the Office Action, the Examiner maintains the rejection of claims 4, 8, and 9 under 35 U.S.C. §112, first paragraph, for the reasons set forth in the previous Office Action. Again, the Examiner states that claims 4, 8, and 9, read on fragments of SEQ ID NO: 3

because the Examiner states that the claims do not recite a nucleic acid "comprising" SEQ ID No. 3. The Examiner states that the claims are not enabled to make a fragment of SEQ ID NO. 3 that is present in the nucleus and which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene or a gene product. The Examiner states that one of ordinary skill in the art would not recognize that Applicants were in possession of the claimed genus. This rejection is respectfully traversed.

By way of this Amendment, the phrase "is set forth in" appearing in claims 4 and 9 has been replaced with the term "comprises."

Accordingly, this rejection should be withdrawn.

Rejection of claims 4-5 and 8-10 under 35 U.S.C. §102(a)

At pages 5-6 of the Office Action, the Examiner maintains the rejection of claims 4-5 and 8-10 under 35 U.S.C. §102(a) as being anticipated by Chano et al. (ONCOGENE, February 14, 2002, 21:1295-1298). The Examiner states that the Declaration under 37 C.F.R. §1.132 filed on January 11, 2008, is insufficient to overcome the rejection of claims 4, 5, and 8-10 based upon Chano et al.

Applicants point out that the Declaration under 37 C.F.R. §1.132 filed on January 11, 2008, incorrectly stated that Tokuhiro Chano, Shiro Ikegawa, and Hidetoshi Okabe are three of six inventors. Applicants regret any confusion caused by this inadvertent error in the Declaration. Tokuhiro Chano, Shiro Ikegawa, and Hidetoshi Okabe, are, in fact, the only inventors of the present application. Applicants submit herewith a Declaration under 37 C.F.R. §1.132 to show that the authors of Chano et al. are the inventors of the present application. As such, Applicants respectfully submit that Chano et al. does not qualify as an invention known or

used by "others" within the meaning of 35 U.S.C. §102(a). The Chano et al. reference, therefore, does not constitute prior art.

Accordingly, this rejection should be withdrawn.

Rejection of claim 10 under 35 U.S.C. §103(a)

At pages 6-7 of the Office Action, the Examiner states that claim 10 remains rejected under 35 U.S.C. §103(a) as being unpatentable over AB059622 in view of Mensik et al (BRITISH J. HAEMATOL., August 1998, 102:768-774) and further in view of Buck et al. (BIOTECHNIQUES (1999) 27(3); 528-536) for the reasons set forth in the previous Office Action. The Examiner states that it would have been obvious for one of ordinary skill in the art to arrive at claim 10 because of the availability in the art of primer design programs and the teaching of Buck that every single primer of the 164 primers tested functioned as expected. The Examiner states that one of ordinary skill in the art would have had a reasonable expectation of success to make the claimed primers given the conventional and routine nature of making primers for polynucleotide analysis and given that the sequence was known in the art at the time the invention was made. This rejection is respectfully traversed.

Claim 10 has been amended to recite primers set forth in "SEQ ID Nos: 5 to 37" instead of "5 to 132." As described in the present application, the primers set forth in SEQ ID NOs: 5 to 37 are selected for analysis of human RB1CC1 gene and/or clinical examination relating to cancer. The cDNA of the nucleic acid encoding the novel protein RB1CC1 according to the present invention was obtained by identifying a gene expressing differentially in U-2 OS osteosarcoma cells and MDR-variant induced cells, conducting amplification employing U-2 OS mRNA as a template using nucleic acid primers described in SEQ ID Nos: 5 to 37, and determining the amino acid

sequence coded for by cDNA of the novel protein and the base sequence (present application, pages 11-12). It should be noted that the function of human RB1CC1 gene must be determined in order to select primers for RB1CC1. None of the cited references describe the function of human RB1CC1. As such, selecting primers for RB1CC1 would not be obvious to one of ordinary skill in the art.

Accordingly, this rejection should be withdrawn.

Rejection of claims 4, 5, and 8 under 35 U.S.C. §102(b)

At pages 7-9 of the Office Action, the Examiner states that claims 4, 5, and 8, are rejected under 35 U.S.C. §102(b) as being anticipated by Nagese et al. (DNA RESEARCH, 1996, 3:321-329) as evidenced by Nomura et al. (DNA RESEARCH, 1994: 1: 27-35), Chano et al. (ONCOGENE, February 14, 2002, 21:1295-1298,) and Appendix 1. The Examiner asserts that Nagese et al. shows the cloning of the cDNA KIAA0203, which the Examiner states is 99.3% identical to SEQ ID NO.: 3 and codes for a protein identical to RB1CC1. The Examiner states that Nagase et al. cloned the cDNA and placed it into the pBluescript SK+ cDNA vector and used to make cDNA libraries that were grown in colonies of cells, as described in Nomura et al. The Examiner states that Chano et al. teaches that RB1CC1 can induce the expression of the RB1 gene. The Examiner acknowledges that the reference does not specifically state that KIAA0203 codes for a protein or polypeptide which is present in the nucleus of human or animal cell and which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene (RB1 gene). The Examiner states, however, that given the teachings of Chano et al., the claimed product appears to be the same as the prior art product. This rejection is respectfully traversed.

As acknowledged by the Examiner, Nagase et al. does not describe a sequence identical to SEQ ID NO: 3. Further, as acknowledged by the Examiner, the reference does not describe a protein or polypeptide which is present in the nucleus of a human or animal cell, or which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene (RB1 gene). The Examiner suggests that the teachings of Chano et al. overcome the deficiencies of Nagase et al. As discussed previously, however, Chano et al. does not qualify as prior art. As such, the Examiner cannot rely on Chano et al. The Examiner's reliance on Chano et al. does not fall within one of the exceptions under M.P.E.P. 2124, and, therefore, cannot be relied upon in this rejection.

It is further noted that the cited references do not alone or in combination, describe the presently claimed vector or the function of RB1CC1. The vector of the present invention is used for expression of the gene. Persistent high expression and/or suppression of expression of the RB1CC1 gene may cause damage to cell proliferation or growth. This information is not disclosed in the cited references. Thus, making a vector comprising the RB1CC1 gene would be difficult for one of ordinary skill in the art based on the teachings of Nagase et al. and/or Chano et al. Accordingly, the cited references do not teach or suggest the claimed vector.

Accordingly, this rejection should be withdrawn.

Rejection of claims 4, 5, 8, and 9 under 35 U.S.C. §103(a)

At pages 9-13 of the Office Action, the Examiner states that claims 4, 5, 8, and 9 are rejected under 35 U.S.C. §103(a) as being unpatentable over AB059622 as evidenced by Chano et al., in view of Olson et al. (U.S. Patent No. 4,889,806) and Sambrook et al. (MOLECULAR CLONING, A LABORATORY MANUAL, Cold Spring Harbor, 1989, pp. 16.3-16.36). The Examiner

acknowledges that AB059622 does not teach a recombinant vector comprising SEQ ID NO: 3, a transformant transformed with the recombinant vector, or a method for producing protein using the recombinant vector. The Examiner states that Olson et al. teaches that with the advent of recombinant DNA and molecular cloning technology, it is now conventional to transfer genetic information into plasmids or vectors constructed *in vitro* and then transferred into host cells and clonally propagated (col. 1, lines 18-24). The Examiner states that Sambrook et al. teaches that cloned genes are conventionally expressed using expression vectors and that expression of cloned proteins has been used. The Examiner states that Sambrook et al. teaches the vectors and methods for producing recombinant proteins by transfecting and culturing cells with the expression vectors (pp. 16.3-16.36). The Examiner states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a recombinant vector with the nucleic acid sequence of B059622, transform the vector into a host cell and produce a protein with the methods of Sambrook et al. and Olson et al. This rejection is respectfully traversed.

As described previously, the Examiner cannot rely on the teachings of Chano et al. because Chano et al. does not qualify as prior art. Furthermore, none of the cited references describe the function of RB1CC1. Persistent high expression and/or suppression of expression of RB1CC1 gene may cause damage to cell proliferation or growth. This information is not disclosed in the cited references. Thus, making a vector comprising the RB1CC1 gene would be difficult for one of ordinary skill in the art based on the teachings of the cited references. As such, the cited references do not render the presently claimed invention obvious.

Accordingly, this rejection should be withdrawn.

Should the Examiner deem that any further action by Applicants or Applicants'

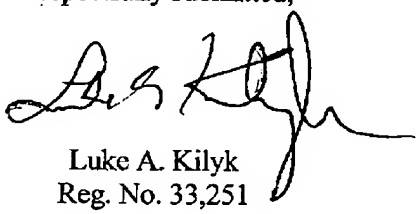
undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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